

REMARKS

The Examiner's Final Office Action mailed November 1, 2007, which rejected all pending claims, has been reviewed. Reconsideration in view of the foregoing amendments and remarks is respectfully requested. Moreover, Applicants have reviewed the Final Office Action of November 1, 2007, and submit that the following Remarks are responsive to all points raised therein. Applicants believe that currently pending claims 21 and 24 are now in form for allowance.

Status of Claims

Claims 21 and 24 are pending in the application. Claim 21 has been amended. Support for the amendment to claim 21 can be found, for example, at paragraph 46 and Example 1 of the specification. Support for new claim 24 can be found, for example, at paragraph 46 and Example 1 of the specification. No new matter has been added.

Information Disclosure Statement

Applicants are submitting a proper information disclosure statement that complies with 37 CFR 1.98(b) as requested by the Examiner.

Rejection of Claims 21-23 under Double Patenting Rejection

Reconsideration is requested of the rejection of claims 21-23 under nonstatutory obviousness-type double patenting as being unpatentable over claims 8-12 of U.S. Patent Application No. 10/682127.

Both the present application and US Patent Application No. 10/682127 are commonly owned. Applicants are submitting a terminal disclaimer for the present application. As such, Applicants request withdrawal of the double patenting rejection and allowance of the claims.

Rejection of Claims 21-23 under 35 USC § 103(a)

Reconsideration is requested of the rejection of claims 21-23 under §103(a) as being unpatentable over Dorn et al. (US Patent No. 6,232,328).

The claimed invention is directed to a composition for control of acarids. Independent claim 21 recites a composition for control of acarids that includes a combination of synergistic effective amounts of from 0.1 to 60% by weight permethrin and from 0.1 to 25% by weight imidacloprid. Independent claim 24 recites a composition for control of acarids comprising a combination of synergistic effective amounts of at least 40% by weight permethrin and from 8 to 10 % by weight imidacloprid.

The subject matter of a claim is prima facie obvious in view of particular references if the Patent Office can demonstrate that (1) the references, alone or together, teach every element of the claims, (2) there is some suggestion or motivation in the knowledge generally available to one of ordinary skill in the art to combine the references, and (3) there is some reasonable expectation of success.

Applicants respectfully submit that Dorn et al. fail to teach or suggest each and every element of independent claims 21 and 24. In particular, Dorn et al. fail to teach or suggest 1) a composition for control of acarids and 2) a composition that includes a combination of synergistic effective amounts of from 0.1 to 60% by weight permethrin and from 0.1 to 25% by weight imidacloprid. Alternatively, for claim 24, Dorn et al. fail to teach or suggest 1) a composition for control of acarids and 2) a composition that includes a combination of synergistic effective amounts of at least 40% by weight permethrin and from 8 to 10% by weight imidacloprid.

Dorn et al. fail to teach or suggest a composition for control of acarids. Dorn et al. teach a method for non-systemically controlling parasitic insects, in particular fleas, lice, and flies. Dorn et al. only describe insects such as Anoplura (sucking lice), Mallophaga (biting lice), Diptera (flies), and Siphonaptera (fleas) (See column 6, lines 31-49). In fact, Dorn et al. do not teach or suggest acarids at all. As described by Dr. Robert Arther in the attached declaration insects and acarids are distinctly different species. Insects, such as fleas, lice, and flies, are

members of the Class Insecta, Subphylum Uniramia; whereas acarids, such as ticks and mites, are members of the Class Arachnida, Subphylum Chelicerata. There are distinct anatomical and physiological differences between these classes and as Dr. Arther notes, compounds that demonstrate activity against insects do not necessarily possess activity against acarids. Therefore, based on the disclosure of Dorn et al., it would not have been obvious to one skilled in the art to use the composition of the present invention to control acarids.

Dorn et al. also fail to teach a composition that includes a combination of synergistic effective amounts of from 0.1 to 60% by weight permethrin and from 0.1 to 25% by weight imidacloprid, or alternatively, at least 40% by weight permethrin and from 8 to 10% by weight imidacloprid. The Examiner states that the ratio and combination of the two elements would have been routine experimentation because it was known that synergism exists between permethrin and imidacloprid. Applicant respectfully disagrees. First, Dorn et al. fail to teach or suggest that the combination of permethrin and imidacloprid possess a synergistic effect. Dorn et al. mention that the "active compounds can be present in the form of a mixture with synergists or other active compounds" (line 5-7, column 17, emphasis added). Dorn et al. specify that the active compounds include insecticides such as pyrethroids (line 7-9, column 17). Dorn et al. do not teach or suggest that the combination of pyrethroids and agonists or antagonists of the nicotinergic acetylcholine receptors are synergistic at all.

Recently, the Supreme Court provided some helpful examples of what combination of elements would be considered obvious or non-obvious. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007). In particular, the Court discussed a case wherein the combination of two pre-existing elements, a radiant-heat burner and a paving machine, did not create new synergy because the combination of the two did no more than they would in separate sequential operation. *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57 (1969). As such, when the combination of two elements, like in this application, provides a synergistic effect, Applicants submit that the combination is non-obvious. For example, as shown in Example 1 of the specification, the combination of

permethrin and imidacloprid produced a faster kill of ticks than either permethrin or imidacloprid alone. For example, on Day 28 of the study, permethrin demonstrated only a 79% kill rate, and imidacloprid exhibited only a 39% kill rate, whereas the combination of permethrin and imidacloprid produced a 92% kill rate. As such, the combination of permethrin and imidacloprid provided a synergistic effect over permethrin and imidacloprid alone.

In addition, Applicant contends that the synergistic combination of permethrin and imidacloprid was unexpected at the time of the invention. As discussed in the attached Declaration by Dr. Arther, at the time of the invention, it was known that chloronicotinyl compounds were effective against insects, however, these chloronicotinyl compounds did not display any activity against ticks or mites, i.e. acarids. Similarly, it was known that pyrethroids showed some activity against both insects and acarids, however, the duration of the activity was short and less than desired. As such, the combination and synergy between permethrin and imidacloprid against acarids was unexpected.

Therefore, Applicants respectfully submit that Dorn et al. do not teach or suggest all of the elements of claims 21 and 24 and that the current invention is novel and non-obvious in view of Dorn et al.

Rejection of Claims 21-23 under 35 USC § 103(a)

Reconsideration is requested of the rejection of claims 21-23 under §103(a) as being unpatentable over Sirinyan et al. (US Patent No. 6,001,858).

Similarly to Dorn et al., Applicants respectfully submit that Sirinyan et al. fail to teach or suggest each and every element of independent claims 21 and 24. In particular, Sirinyan et al. fail to teach or suggest 1) a composition for control of acarids and 2) a composition that includes a combination of synergistic effective amounts of from 0.1 to 60% by weight permethrin and from 0.1 to 25% by weight imidacloprid. Alternatively, for claim 24, Sirinyan et al. fail to teach or suggest 1) a composition for control of acarids and 2) a composition that includes a combination of synergistic effective amounts of at least 40% by weight permethrin and from 8 to 10% by weight imidacloprid.

Sirinyan et al. fail to teach or suggest a composition for control of acarids. Sirinyan et al. teach a composition for the dermal control of parasitic insects, in particular fleas, lice, and flies. Sirinyan et al. only describe insects such as Anoplura (sucking lice), Mallophaga (biting lice), Diptera (flies), and Siphonaptera (fleas) (See column 7, line 65 to column 8, line 15). In fact, Sirinyan et al. do not teach or suggest acarids at all. As described by Dr. Robert Arther in the attached declaration insects and acarids are distinctly different species. Insects, such as fleas, lice, and flies, are members of the Class Insecta, Subphylum Uniramia; whereas acarids, such as ticks and mites, are members of the Class Arachnida, Subphylum Chelicerata. There are distinct anatomical and physiological differences between these classes and as Dr. Arther notes, compounds that demonstrate activity against insects do not necessarily possess activity against acarids. Therefore, based on the disclosure of Sirinyan et al., it would not have been obvious to one skilled in the art to use the composition of the present invention to control acarids.

Sirinyan et al. also fail to teach a composition that includes a combination of synergistic effective amounts of from 0.1 to 60% by weight permethrin and from 0.1 to 25% by weight imidacloprid, or alternatively, at least 40% by weight permethrin and from 8 to 10% by weight imidacloprid. The Examiner states that the ratio and combination of the two elements would have been routine experimentation because it was known that synergism exists between permethrin and imidacloprid. Applicant respectfully disagrees. First, Sirinyan et al. fail to teach or suggest that the combination of permethrin and imidacloprid possess a synergistic effect. Sirinyan et al. mention the "it is also possible for further active substances to be present with nicotiny compounds" (line 27-28, column 8). Sirinyan et al. also mention that the active compounds include insecticides such as pyrethroids (line 29-31, column 8). In fact, Sirinyan et al. do not teach or suggest that a combination of pyrethroids and agonists or antagonists of the nicotinergerg acetylcholine receptors are synergistic at all.

In addition, as discussed above, Applicant contends, that unlike suggested by the Examiner, the synergistic combination of permethrin and imidacloprid was

unexpected at the time of the invention. As discussed in the attached Declaration by Dr. Arther, at the time of the invention, it was known that chloronicotinyl compounds were effective against insects, however, these chloronicotinyl compounds did not display any activity against ticks or mites, i.e. acarids. Similarly, it was known that pyrethroids showed some activity against both insects and acarids, however, the duration of the activity was short and less than desired. As such, the combination and synergy between permethrin and imidacloprid against acarids was unexpected.

Therefore, Applicants respectfully submit that Sirinyan et al. do not teach or suggest all of the elements of claims 21 and 24 and that the current invention is novel and non-obvious in view of Sirinyan et al.

Conclusion

In view of the above, Applicants respectfully submit that the pending claims are novel and not obvious over the cited references and request withdrawal of all rejections and allowance of the claims.

The Commissioner is hereby authorized to charge any fee deficiency or credit any overpayment in connection with this amendment to Deposit Account No. 50-4260.

Respectfully submitted,
/JESSICA MONACHELLO/
Jessica Monachello
Reg. No. 58,015
BAYER HEALTHCARE LLC
P.O. Box 390
Shawnee Mission, KS 66201
Tel: 913-268-2038
Fax: 913-268-2889